4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2012-N-0376]

Sanofi-aventis, U.S., LLC; Withdrawal of Approval of a New Drug Application for OFORTA

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is withdrawing approval of a new drug application (NDA) for OFORTA (fludarabine phosphate) Tablets held by sanofi-aventis, U.S., LLC (sanofi-aventis), 55 Corporate Dr., Bridgewater, NJ 08807-0977. Sanofi-aventis has voluntarily requested that approval of this application be withdrawn, thereby waiving its opportunity for a hearing.

DATES: Effective December 31, 2011.

FOR FURTHER INFORMATION CONTACT:

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SUPPLEMENTARY INFORMATION: FDA approved OFORTA (fludarabine phosphate) Tablets on December 18, 2008, under the Agency's accelerated approval regulations, 21 CFR

part 314, subpart H. OFORTA is approved for use as a single agent for the treatment of adult patients with B-cell chronic lymphocytic leukemia whose disease has not responded to or has progressed during or after treatment with at least one standard alkylating agent-containing regimen. On February 10, 2011, FDA requested that sanofi-aventis voluntarily withdraw OFORTA (fludarabine phosphate) Tablets from the market, because the postmarketing study required as a condition of approval under subpart H had not been completed and clinical benefit had not been verified. In a letter dated June 24, 2011, sanofi-aventis requested that FDA withdraw approval of NDA 22-273 for OFORTA (fludarabine phosphate) Tablets under § 314.150(d), noting the lack of commercial demand for OFORTA and significant challenges to completing the postmarketing study. In that letter, sanofi-aventis also waived its opportunity for a hearing, otherwise provided under §§ 314.150 and 314.530. In a letter dated July 8, 2011, the Agency acknowledged sanofi-aventis' agreement to permit FDA to withdraw approval of OFORTA under § 314.150(d) and waive its opportunity for a hearing. The Agency noted that the required postmarketing study had not been completed and clinical benefit had not been verified.

Therefore, under section 505(e) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 355(e)) and § 314.150(d), and under authority delegated by the Commissioner to the Director, Center for Drug Evaluation and Research, approval of NDA 22-273, and all amendments and supplements thereto, is withdrawn (see DATES). Distribution of this product in interstate commerce without an approved application is illegal and subject to regulatory action (see sections 505(a) and 301(d) of the FD&C Act (21 U.S.C. 355(a) and 331(d)).

Dated: April 5, 2012.

Janet Woodcock,
Director,
Center for Drug Evaluation and Research.

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